

PRIA Fee Category Table – Registration Division – Amendments

Table 5.

EPA No.	New CR No.	Action	Decision Review Time (Months)[HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote1"]	FY'17 & FY'18 Registration Service Fee (\$)
[HYPERLINK "http://www2.epa.gov/pria-fees/r340-pria-fee-category"]	60	Amendment requiring data review within RD (e.g., changes to precautionary label statements); includes adding/modifying pest(s) claims for up to 2 target pests, excludes products requiring or citing an animal safety study. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote3"]	4	4,988
R341	61 (New)	Amendment requiring data review within RD (e.g., changes to precautionary label statements), includes adding/modifying pest(s) claims for greater than 2 target pests, excludes products requiring or citing an animal safety study. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-	6	5,988

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		amendments" \\ "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \\ "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/r345-pria-fee-category"]	62	Amending on-animal products previously registered, with the submission of data and/or waivers for only: <ul style="list-style-type: none"> • Animal safety and • Pest(s) requiring efficacy⁽⁴⁾ and/or • Product chemistry and/or • Acute toxicity and/or • Child resistant packaging [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \\ "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \\ "footnote3"] 	7	8,820

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[HYPERLINK "http://www2.epa.gov/pria-fees/r350-pria-fee-category"]	63	Amendment requiring data review in science divisions (e.g., changes to REI, or PPE, or PHI, or use rate, or number of applications; or add aerial application; or modify GW/SW advisory statement) [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote3"]	9	13,226
[HYPERLINK "http://www2.epa.gov/pria-fees/r351-pria-fee-category"]	64	Amendment adding a new unregistered source of active ingredient. [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote3"]	8	13,226
[HYPERLINK "http://www2.epa.gov/pria-fees/r352-pria-fee-category"]	65	Amendment adding already approved uses; selective method of support; does not apply if the applicant owns all cited data [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-	8	13,226

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		registration-division-amendments" \l "footnote2"] [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote3"]		
[HYPERLINK "http://www2.epa.gov/pria-fees/r371-pria-fee-category"]	66	Amendment to Experimental Use Permit; (does not include extending a permit's time period) [HYPERLINK "http://www2.epa.gov/pria-fees/pria-fee-category-table-registration-division-amendments" \l "footnote3"]	6	10,090

¹A decision review time that would otherwise end on a Saturday, Sunday, or federal holiday, will be extended to end on the next business day.

²(a) EPA-initiated amendments shall not be charged registration service fees. (b) Registrant-initiated fast-track amendments are to be completed within the timelines specified in FIFRA Section 3(c)(3)(B) and are not subject to registration service fees. (c) Registrant-initiated fast-track amendments handled by the Antimicrobials Division are to be completed within the timelines specified in FIFRA Section 3(h) and are not subject to registration service fees. (d) Registrant initiated amendments submitted by notification under PR Notices, such as PR Notice 98-10, continue under PR Notice timelines and are not subject to registration service fees. (e) Submissions with data and requiring data review are subject to registration service fees.

³Where the action involves approval of a new or amended label, on or before the end date of the decision review time, the Agency shall provide to the applicant a draft accepted label, including any changes made by the Agency that differ from the applicant-submitted label and relevant supporting data reviewed by the Agency. The applicant will notify the Agency that the applicant either (a) agrees to all of the terms associated with the draft accepted label as amended by the Agency and requests

that it be issued as the accepted final Agency-stamped label; or (b) does not agree to one or more of the terms of the draft accepted label as amended by the Agency and requests additional time to resolve the difference(s); or (c) withdraws the application without prejudice for subsequent resubmission, but forfeits the associated registration service fee. For cases described in (b), the applicant shall have up to 30 calendar days to reach agreement with the Agency on the final terms of the Agency-accepted label. If the applicant agrees to all of the terms of the accepted label as in (a), including upon resolution of differences in (b), the Agency shall provide an accepted final Agency-stamped label to the registrant within 2 business days following the registrant's written or electronic confirmation of agreement to the Agency.

⁴For the purposes of classifying proposed registration actions into PRIA categories, "pest(s) requiring efficacy" are: public health pests listed in PR Notice 2002-1, livestock pests (e.g. Horn flies, Stable flies), wood-destroying pests (e.g. termites, carpenter ants, wood-boring beetles) and certain invasive species (e.g. Asian Longhorned beetle, Emerald Ashborer). This list may be updated/refined as invasive pest needs arise. To determine the number of pests for the PRIA categories, pests have been placed into groups (general; e.g., cockroaches) and pest specific (specifically a test species). If seeking a label claim against a pest group (general), use the group listing below and each group will count as 1. The general pests groups are: mites, dust mites, chiggers, ticks, hard ticks, soft ticks, cattle ticks, scorpions, spiders, centipedes, lice, fleas, cockroaches, keds, bot flies, screwworms, filth flies, blow flies, house flies, flesh flies, mosquitoes, biting flies, horse flies, stable flies, deer flies, sand flies, biting midges, black flies, true bugs, bed bugs, stinging bees, wasps, yellow jackets, hornets, ants (excluding carpenter ants), fire and harvester ants, wood destroying beetles, carpenter ants, termites, subterranean termites, dry wood termites, arboreal termites, damp wood termites and invasive species. If seeking a claim against a specific pest without a general claim then each specific pest will count as 1.